



Market size and sales pattern of tuberculosis drugs in the Philippines

T. Islam,¹ C. van Weezenbeek,² R. Vianzon,³ A. M. C. G. Garfin,³ T. Hiatt,¹ W. J. Lew,⁴ K. Tisocki⁵

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Objectives: To identify the availability, types and quantity of anti-tuberculosis drugs in the public and private sectors from 2007 to 2011 in the Philippines.

Methods: Analysis of the procurement of and sales data on anti-tuberculosis drugs from both the public and private sectors from 2007 to 2011.

Results: Publicly procured anti-tuberculosis drugs were sufficient to treat all reported new tuberculosis (TB) cases from 2007 to 2011 in the Philippines. Nevertheless, the volume of anti-tuberculosis drugs in the private sector would have sufficed for the intensive phase of treatment for an additional 250 000 TB patients annually, assuming compliance with national treatment guidelines. Fixed-dose combination drugs comprised the main bulk (81%) of private market sales, while sales of loose drugs decreased over the years. Combining public and private sales in 2011, 484 725 new TB patients, i.e., 2.4 times the number of notified cases, could have been placed on treatment and treated for at least the intensive phase. Key second-line drugs are not available in the private market, making it impossible to design an adequate treatment regimen for multidrug-resistant TB (MDR-TB) in the private sector.

Conclusion: An enormous quantity of anti-tuberculosis drugs was channelled through the private market outside the purview of the Philippine National Tuberculosis Control Program, suggesting significant out-of-pocket expenditure, severe underreporting of TB cases and/or misuse of drugs due to overdiagnosis and overtreatment.

The Philippines is one of the top 10 high tuberculosis (TB) burden countries in the world.¹ The country also faces a significant burden of multidrug-resistant tuberculosis (MDR-TB). In 2012, the estimated TB incidence was 260 000, with an uncertainty interval ranging from 210 000 to 310 000.¹ The estimated number of MDR-TB cases among notified pulmonary TB cases in 2012 was 8400 (range 6000–11 000) among new and 4900 (3400–6800) among retreatment cases, with a yearly total of 13 300 cases.¹

In 1996, the Philippine National Tuberculosis Control Programme (NTP) introduced DOTS, a World Health Organization (WHO) endorsed strategy for TB control.² Countrywide coverage of DOTS services was achieved by the end of 2002, with free diagnosis and treatment for smear-positive patients.³ However, several studies provided strategic evidence to show that the majority of individuals with TB symptoms preferred to seek care in the private sector, although government sector services were free.^{4,5} It is well known that the Philippines has a large private sector, with several thousand individual medical practitioners and over a thousand

private hospitals of various sizes.^{3,6} Anti-tuberculosis drugs are widely available in the private market in the Philippines.

Understanding private sector dynamics could provide new insights into the burden of disease, use of public services and the whereabouts of 'missing cases'. The primary objective of the present study was to identify the availability, types and quantities of anti-tuberculosis drugs in the public and private sectors in the Philippines from 2007 to 2011. For this study, the private sector was defined as drugs channelled outside government procurement services, irrespective of whether the drugs were used by public or private providers.

METHODS

We collected and analysed the procurement and sale data of anti-tuberculosis drugs in the public and private sectors during the period 2007–2011.

First-line anti-tuberculosis drugs

Data collection in the public sector

We collected public sector procurement data for 2007–2011 from the Central Bids and Awards Committee (COBAC) database in terms of the number and type of treatment units purchased (Figure 1). In 2007 and 2008, the Philippines NTP also procured first-line anti-tuberculosis drugs from the Global Drug Facility (GDF), an initiative of the Stop TB Partnership that was established to expand access to low-price, high-quality anti-tuberculosis drugs.⁷ We collected the 2007 and 2008 data from the GDF on-line database.

Data collection in the private sector

Private sector data of anti-tuberculosis drug sales from 2007 to 2011 were collected in terms of dosage units of sales from the database of IMS Health Philippines, a branch of IMS Health International (<http://www.imshealth.com/portal/site/imshealth>). IMS collects drug sales data from large distributors and manufacturers and panel drug stores and hospitals in the Philippines on a monthly basis.

All data were taken from the routine recording and reporting systems of COBAC, GDF and IMS Health Philippines. Ethics approval was therefore not required for the study.

RESULTS

First-line anti-tuberculosis drugs in the public sector

The NTP uses TB patient kits that contain all the anti-tuberculosis drugs needed for a full course of treatment.

AFFILIATIONS

¹ Stop TB Unit, World Health Organization, Western Pacific Regional Office, Manila, The Philippines

² KNVC Tuberculosis Foundation, The Hague, The Netherlands

³ National Center for Disease Prevention and Control, Department of Health, Manila, The Philippines

⁴ World Health Organization, WHO Representative Office Philippines, Manila, The Philippines

⁵ Essential Medicines and Health Technologies Unit, World Health Organization, Western Pacific Regional Office, Manila, The Philippines

CORRESPONDENCE

Tauhid Islam
Stop TB and Leprosy Elimination
World Health Organization
Western Pacific Regional Office
1000 Manila, The Philippines
Tel: (+632) 528 9720
Fax: (+632) 521 1036
e-mail: islamt@wpro.who.int

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KEY WORDS

private sector; public-private mix; multidrug-resistant tuberculosis; fixed-dose combination

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Forecasting/quantification

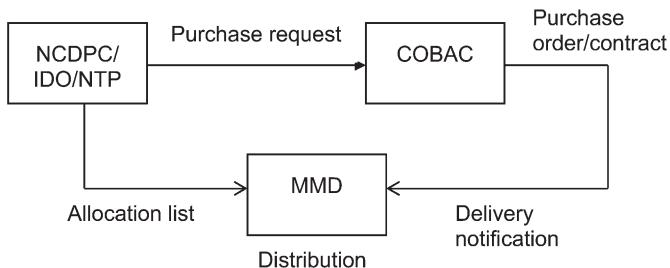


FIGURE 1 TB drug procurement flow in the public sector in the Philippines. NCDPC = National Center for Disease Prevention and Control; IDO = Infectious Disease Office; NTP = National Tuberculosis Programme; COBAC = Central Bids and Awards Committee; MMD = Material Management Division.

Two types of patient kits were used: 1) Category I and III kits (2HRZE/4HR)* for new TB cases, and 2) Category II kit (2 HRZES/1HRZE/5HRE) for retreatment TB cases.

Table 1 shows the public procurement of anti-tuberculosis drugs in terms of patient kits during 2007–2011. The total number of procured drugs for new TB cases was sufficient to cover all notified cases from 2008 to 2011, with a substantial buffer stock. Procurement for retreatment TB cases was irregular, not always centralised and not enough to meet needs.

The total cost of public procurement of first-line anti-tuberculosis drugs ranged from US\$2.3 million in 2007 to US\$13 million in 2010. These differences in cost were due to the increasing patient load and the procurement of buffer stocks in different quantities. Prices also varied in different years. The unit cost of publicly procured Category I and III kits varied from 1469 Philippine pesos (approximately US\$37) in 2008 to 950 Philippine pesos (around US\$23.75) in 2011. The price of the kit procured through GDF was US\$17.6 in 2007 and US\$20.73 in 2008.

First-line anti-tuberculosis drugs in the private sector

In the private sector, 38 anti-tuberculosis drug formulations of 28 different strengths were available in 2011. The number of available

*H = isoniazid; R = rifampicin; Z = pyrazinamide; E = ethambutol; S = streptomycin. Numbers before the letters indicate the duration in months of the phase of treatment.

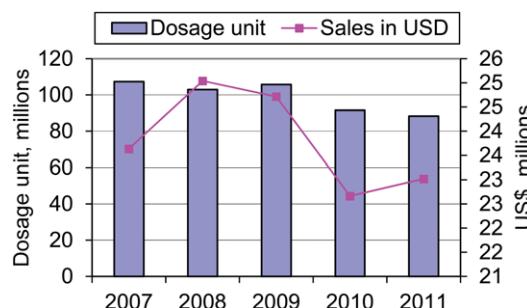


FIGURE 2 Yearly sales of first-line anti-tuberculosis drugs in the private sector, the Philippines, 2007–2011. USD = US dollar.

strengths and products decreased over the period. The number of products decreased from 53 products in 2007 to 38 in 2011. Available strengths decreased from 42 in 2007 to 28 in 2011. Availability of anti-tuberculosis drug formulations with a single active ingredient decreased significantly, from 21 in 2007 to 13 in 2011. During the same period, the availability of fixed-dose combination drugs (FDC) increased from 4 in 2007 to 7 in 2011.

A huge quantity of first-line anti-tuberculosis drugs is being channelled through the private market. Average yearly sales (2007–2011) are equivalent to US\$24 million based on the manufacturer's price (Figure 2). The actual procurement price may be different, however, due to pooled procurement mechanisms created by large pharmacy chains. Chain drug stores are the most common channel for drugs, making up 58% of private procurement, followed by independent drug stores (18%). Private hospitals, dispensing doctors and industrial facilities account for respectively 2%, 5% and 7% (Figure 3).

FDC sales in 2007–2011 represent 81% of total sales, with 4-, 3- and 2-drug FDCs accounting for respectively 43%, 29% and 9%. Over the years, the proportion of sales of FDCs increased from 69% in 2007 to 89% in 2011. On the other hand, the sale of loose drugs decreased over the years ($R^2 0.93$), from 25% in 2007 to 8% in 2011. There are variations in FDC sales, but the total quantity of dosage units has remained similar over the years. The highest sales of FDCs were observed in 2009 (Figure 4).

According to the national guidelines, the standard regimen used in the Philippines for new TB patients (Category I and III kits) contains drugs for 2 months of 4FDC and 4 months of 2FDC, assuming an average patient weight of 38–54 kg, for which national

TABLE 1 Anti-tuberculosis drug procurement in the public sector in the Philippines, 2007–2011

Procurement year and equivalent cohort year*	2007	2008	2009	2010	2011
Category I & III kits					
GDF	130 784	64 408			
Local procurement		114 544	256 810	378 000	228 157
Total	130 784	178 952	256 810	378 000	228 157
Corresponding notified new and relapse cases*	139 603	146 565	166 323	195 560	203 826
Difference between drugs procured and TB cases notified	−8 819	32 387	90 487	182 440	24 331
Category II kits					
GDF		3 205			
Local procurement	—	3 205	—	16 372	—
Total	—	3 205	—	16 372	—
Corresponding notified retreatment cases*	6 289	6 602	8 066	10 528	13 103
Difference between drugs procured and TB cases notified	−6 289	−3 397	−8 066	5 844	−13 103
Total cost, US\$ in millions	2.3	5.5	12	13	5.5

*It was assumed that drugs procured were for the following year's patients. Notified cases are offset by 1 year (cohort year−1) to align cohorts with the procurement year of the drugs they consumed.

GDF = Global Drug Facility.

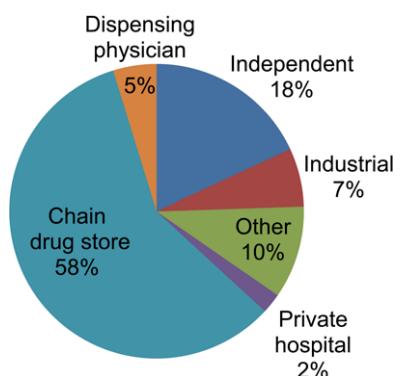


FIGURE 3 Sales channels for anti-tuberculosis drugs in the private sector, the Philippines, 2007–2011.

guidelines recommend three 4FDC tablets daily during the 2-month intensive phase and three 2FDC tablets during the 4-month continuation phase of treatment. Per the standard treatment regimen, the ratio of 4FDCs to 2FDCs is thus 1:2. In the private sector, the ratio of 4FDCs and 2FDCs is 5:1.

Treatment practices in the private sector in the Philippines are not fully known. It is assumed that 4FDCs are used for the 2-month intensive phase. In the continuation phase, 3FDCs, 2FDCs and single-ingredient anti-tuberculosis drugs can be used. Only 4FDCs are available in a single form, but other formulations (3FDCs, 2FDCs and single ingredients) are available in multiple strengths and forms. Translating 4FDC sales into the number of patients that could be treated for the intensive phase may give us an idea of the number who could be initiated on anti-tuberculosis treatment in the private sector. Obviously, this number can only be used to obtain an idea of the scale of drug sales, and needs to be interpreted with caution. In 2011, private sector sales would have been able to be used to initiate treatment in 256 568 patients. This is a consistent finding in the period 2008–2010, with an average capacity to initiate treatment for 250 000 patients, with around 40 million units of 4FDCs from private sector sales. For previously treated patients, using 2 months of streptomycin as proxy, in 2011 private sales would have sufficed to initiate treatment for 3511 patients. For other years, this figure ranged from 3420 to 4888 (Table 2).

Second-line anti-tuberculosis drugs

The NTP procures second-line drugs such as capreomycin, kanamycin, levofloxacin, ofloxacin, prothionamide, cycloserine and para-aminosalicylic acid (PAS) from the GDF. Among these, IMS Health Philippines data capture only private sector sales of fluoroquinolones, which are difficult to interpret as they are widely used for

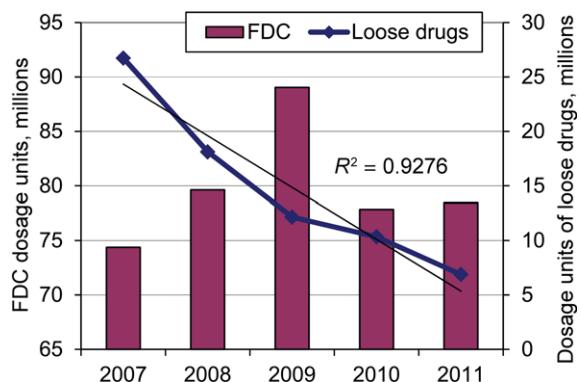


FIGURE 4 Trend of single ingredient anti-tuberculosis drug sales in the private sector, the Philippines, 2007–2011. FDC = fixed-dose combination.

diseases other than MDR-TB. We found that many second-line drugs were not registered with the Philippines Food and Drug Administration (<http://www.fda.gov.ph/database>). Furthermore, it is important to note that not all registered products may be available on the market due to low demand. For example, all injectables were registered in the Philippines, whereas oral bacteriostatic drugs were not registered, apart from a single product of cycloserine. Table 3 shows the registration status of second-line anti-tuberculosis drugs and their grouping per WHO guidelines.⁸

DISCUSSION

Public sector data cover only central procurement by COBAC and not sub-national procurement data; they thus represent the minimum quantities available through the public sector. Nonetheless, the data show that this public channel was sufficient to offer treatment to all notified new TB patients as per the national policy. At the same time, private sales are significant, with a clear tendency to prefer FDCs over the use of single ingredients, which is a positive development in itself, provided that patients are properly managed. However, the ratio of sales of 4FDCs to 2FDCs on the private market is 5:1, which does not reflect compliance with the national guidelines, but rather indicates that a large proportion of patients do not follow the national standard regimen or complete the continuation phase of treatment. The most remarkable finding is that the private market alone could initiate anti-tuberculosis treatment for around 250 000 patients per year. This sales pattern is consistent over the study years (2007–2011). Private and public sector sales in 2011 together could have covered the intensive phase of treatment for 484 725 new TB patients, 2.4 times the number of notifications for that year.

These findings lead to the question as to why there is such

TABLE 2 Quantities of dosage units of anti-tuberculosis drugs and approximate numbers of patients who could have been initiated on treatment using drugs obtained in the private sector, 2007–2011

	2007	2008	2009	2010	2011
4FDC	39 021 040	41 895 860	46 120 220	42 456 960	43 103 500
2FDC (all strengths and forms)	7822448	9152052	10095688	7984532	8657360
Number of new TB patients who could have received the 2-month intensive phase of treatment	232 268	249 380	274 525	252 720	256 568
Streptomycin (1 g)	210 410	273 740	231 580	226 260	191 510
Number of previously treated TB patients who could have been initiated on treatment	3 757	4 888	4 135	4 040	3 420

4 = 4-drug; FDC = fixed-dose combination; 2 = 2-drug; TB = tuberculosis.

TABLE 3 Registration status of second-line anti-tuberculosis drugs in the Philippines

Group	Description	Drugs	Registered	Products registered
2	Injectable anti-tuberculosis drugs	Kanamycin	Yes	2
		Amikacin	Yes	36
		Capreomycin	Yes	3
3	Fluoroquinolones	Moxifloxacin	Yes	9
		Levofloxacin	Yes	120
4	Oral bacteriostatic second-line anti-tuberculosis drugs	Cycloserine	Yes	1
		Ethionamide	No	NA
		Prothionamide	No	NA
		PAS	No	NA
		Terizidone	No	NA
5	Anti-tuberculosis drugs with unclear efficacy (not recommended by the WHO for routine use)	Linezolid	Yes	4

PAS = para-aminosalicylic acid; WHO = World Health Organization.

significant private sector involvement in a setting with sufficient free public sector anti-tuberculosis drugs. There are several limitations to our study that could explain part of the situation. First, as we did not analyse the distribution of public anti-tuberculosis drugs in relation to notifications, we cannot be sure that sufficient quantities were available in all parts of this challenging geography of more than 7000 islands. Second, IMS data are based on data provided by companies registered with IMS. The leak through non-IMS-registered manufacturers seems negligible, as panel data show that only 2% of the total projected sales come from non-subscriber manufacturers. Third, we collected only drug procurement and sales data, and not data on drug consumption by patients, and loss, damage and expiry of drugs were not considered in the analysis. However, the pattern of anti-tuberculosis drug sales over the years remains the same, indicating a minimum loss of drugs, also taking into account the profit-maximising approach of the private sector.

Other reasons may also have played an important role. First, incidence estimates can be very uncertain,¹ and thus the actual annual caseload may be higher than 260 000. Second, it is well known that the private sector in the Philippines is substantial and that even poor patients tend to seek care from private providers.^{9–13} These patients are not initially notified, although some may eventually seek care with public services and are notified when they can no longer afford out-of-pocket expenditure for private consultations and drugs. TB has not been included in the list of notifiable diseases by the Department of Health since 2001, and there is in fact no inbuilt mechanism in the government data collection system to capture the substantial numbers of TB cases managed outside the NTP. The introduction of compulsory TB notification seems one of the most obvious solutions to the ‘missing cases’ issue. Third, it is possible that in some regions patients experience barriers in accessing free diagnosis and treatment. Lastly, our figures may also indicate misuse of drugs in inadequate regimens in the private sector, such as overdosing, prolonged treatment duration, overdiagnosis or extended use when patients move from the private to the public sector. The study by Portero and Rubio favours this assumption: their study showed that in the Philippines private sector, TB was diagnosed mainly using X-ray (87.9%) and was usually treated with inappropriate anti-tuberculosis regimens (89.3%).¹²

Similar findings were published by Wells et al. in an article that examined the private sectors of 10 high TB burden countries. Their study illustrated that 86% of incident cases in 2008

could have been treated by first-line drugs in the private market in the Philippines.¹⁴ Studies in Greece and Spain using drug consumption data provide evidence of major underreporting of TB cases.^{15,16}

Although the Philippines initiated public-private mix (PPM) approaches very early,^{6,17–19} the best modality for engaging private for-profit providers remains a topic of discussion. Our study indicates that PPM coverage is limited and that immense out-of-pocket expenditure is a reality for TB patients. It should be noted that 42% of the Filipino population lives on US\$2 a day.²⁰ Portero et al. pointed out that lower socio-economic groups have a greater tendency to self-treat in the Philippines.²¹

The MDR-TB burden in the Philippines is also high and may reflect the misuse of anti-tuberculosis drugs in the private sector. According to the drug resistance survey conducted in 2004, MDR-TB prevalence was 20.9% (95% confidence interval 13.0–32.0) among retreatment cases.²² Our findings show that the private sector cannot prescribe adequate MDR-TB treatment regimens, as crucial second-line anti-tuberculosis drugs such as PAS, ethionamide, prothionamide and terizidone are not registered in the Philippines and are therefore not available for sale. Private providers are thus obliged to refer patients to the NTP, or to create suboptimal regimens, which may lead to extensively drug-resistant TB (XDR-TB). Although the Philippines is rapidly expanding its programmatic management of MDR-TB, this situation is of serious concern.

CONCLUSION

Approximately 100 million units of first-line anti-tuberculosis drugs are channelled through the private drug market in the Philippines every year. This involves significant out-of-pocket expenditures that are likely to result in patients interrupting and changing treatment regimens, and it may contribute to the development and spread of anti-tuberculosis drug resistance. In the current situation, private sector treatment of MDR-TB may lead to unnecessary deaths and the emergence of XDR-TB due to the unavailability of key oral second-line anti-tuberculosis drugs. The findings of this study call for mandatory notification, strengthening of regulatory approaches and expansion of PPM programmes for both drug-susceptible and -resistant TB.

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Objectifs : Identifier la disponibilité, le type et la quantité des médicaments antituberculeux dans le secteur public et privé de 2007 à 2011 aux Philippines.

Méthodes : Analyse des commandes et des ventes de médicaments antituberculeux du secteur public et privé de 2007 à 2011.

Résultats : Les médicaments antituberculeux du secteur public ont suffi à traiter tous les nouveaux cas de tuberculose (TB) dépistés de 2007 à 2011 aux Philippines. Cependant, le volume de médicaments antituberculeux du secteur privé aurait suffi à démarrer le traitement de 250 000 autres patients tuberculeux chaque année en admettant que le traitement administré ait été conforme aux directives nationales de traitement en phase intensive. Les médicaments combinés à dose fixe représentaient la majorité des ventes du secteur privé (81%), tandis que les ventes de médicaments uniques ont diminué au fil des

années. En combinant les ventes publiques et privées en 2011, un total de 484 725 nouveaux patients aurait pu débuter un traitement au moins en ce qui concerne la phase intensive, ce qui correspond à 2,4 fois le nombre de cas notifiés. Les principaux médicaments de deuxième ligne ne sont pas disponibles dans le secteur privé, ce qui ne permet pas de concevoir un protocole de traitement approprié pour la TB multirésistante.

Conclusion : Une quantité énorme de médicaments antituberculeux a été distribuée à travers le secteur privé en dehors du Programme national de lutte contre la tuberculose des Philippines, ce qui suggère des dépenses importantes pour les patients, une notification très insuffisante des cas et/ou une mauvaise utilisation des médicaments liée à des diagnostics en excès et à des traitements inutiles.

Objetivos: Investigar la disponibilidad, los tipos y las cantidades de medicamentos antituberculosos accesibles en los sectores público y privado en las Filipinas del 2007 al 2011.

Métodos: Se practicó un análisis de los mecanismos de adquisición de los medicamentos antituberculosos y de los registros de las ventas en el sector público y el sector privado del 2007 al 2011.

Resultados: Los medicamentos antituberculosos obtenidos en el sector público fueron suficientes para tratar todos los casos nuevos notificados del 2007 al 2011 en las Filipinas. Además, el volumen de medicamentos en el mercado privado fue suficiente para iniciar el tratamiento de otros 250 000 pacientes con TB cada año, si se supone la conformidad con las pautas nacionales de tratamiento de la fase intensiva. Los medicamentos en combinación de dosis fijas correspondían a la mayor parte de las ventas en el sector privado (81%) y las ventas de los medicamentos con ingredientes únicos disminuyeron

con el transcurso de los años. Al combinar las ventas en ambos sectores en el 2011, se podría haber iniciado el tratamiento y completado por lo menos la fase intensiva de 484 725 casos nuevos de TB, lo cual corresponde a 2,4 veces el número de los casos notificados. Los principales medicamentos de segunda línea no están al alcance en el mercado privado, lo cual hace imposible establecer un régimen adecuado de tratamiento de la TB multidrogorresistente en este sector.

Conclusión: Una gran cantidad de medicamentos antituberculosos se canalizaron por conducto del mercado privado, por fuera del ámbito del Programa Nacional contra la Tuberculosis de las Filipinas, lo cual indica costos directos considerables para los pacientes, una infranotificación excesiva de los casos de TB o el uso inapropiado de los medicamentos debido al exceso de diagnóstico y el exceso de tratamiento.